REMARKS

Claims 2 and 3 are currently cancelled. Claims 4-10 were previously withdrawn. Applicants reserve the right to file continuation or divisional applications directed to the cancelled and withdrawn subject matter. Claim 1 is currently amended. Support for the amendment can be found throughout the specification, specifically in the claims as originally filed. No new matter has been added. Claim 1 is currently under consideration.

Rejection Under 35 U.S.C. §112, First Paragraph

Claims 1-3 are rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. The Examiner states that the claims encompass a method that uses selective immune down regulation (SIDR), but that the only disclosed methods/reagents for establishing SIDR are those listed on page 17 of the specification. The Examiner then states:

> The reagent used in the claimed method is defined in terms of a functional activity with no structural information provided. There is no disclosed (or known) correlation between the functional activity and the structure of an agent that can induce "selective immune down regulation."
>
> ***
>
> The SIDR requires specific modes of administration and/or additional agents to induce SIDR (see specification, page 17). However, the only such reagents/methods for establishing SIDR are those disclosed in the specification, page 17.

Office Action pages 2-5.

35 U.S.C. §112, first paragraph requires that a specification enable one skilled in the art to make and use the claimed invention. A specification fails to meet this requirement if the specification fails to provide sufficient information regarding the claimed subject matter to enable a skilled artisan to make and use the claimed invention. "However, to comply with 35 U.S.C. §112, first paragraph, it is not necessary to 'enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect.' CFMT, Inc. v. Yieldup Int'l Corp., 349 F.3d 1333, 1338, 68 USPQ2d 1940, 1944 (Fed. Cir. 2003)." (MPEP §2164). To determine if sufficient information is provided, one must inquire whether the claimed invention can be practiced without undue experimentation.

MPEP §2164.01. That some experimentation may be required is not fatal because the issue is whether the experimentation is undue. In re Vaeck, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991).

Applicants respectfully traverse the rejection and assert that the claims are fully enabled. However, solely in an effort to promote prosecution, claim 1 has been amended to consolidate the limitations of claims 2 and 3 in reciting a process for producing selective immune down regulation in a subject "comprising the step of orally administering to said subject a reagent or a combination of reagents comprising components or fragments of streptococcus bacteria." In response to the Examiner's remarks that the reagent used in the claimed method is defined in terms of a functional activity with no structural information, Applicants assert that claim 1 now recites a physical description of the source producing SIDR. Claim 1 now specifically recites components or fragments of streptococcal bacteria as the reagent or combination of reagents for producing SIDR. The specification describes the treatment and prevention of conditions resulting from infection with streptococcal bacteria. Specification page 32, lines 19-38. Thus, contrary to the Examiner's assertion, the reagent used in the claimed method (i.e., components or fragments of streptococcal bacteria) is not "defined in terms of a functional activity with no structural information provided," but rather is now described in terms of specified structure.

The Examiner states on page 4 of the specification that "The SIDR requires specific modes of administration..." Amended claim 1 now recites a specific mode of administration (oral administration) to induce SIDR. The passage at page 32, lines 19-38 of the specification refers back to previous portions of the specification in describing modes of administration, specifically oral administration. See, for example, specification pages 23-25. Currently amended claim 1 now requires a specific mode of administration.

Amended claim 1 now recites both a physical description that of the source of producing SIDR and a specific mode of administration. These limitations are clearly described in the specification, as cited above. One of skill in the art would thus conclude that Applicants were in possession of the claimed subject matter. Claim 1 therefore satisfies the written description requirement of 35 U.S.C. § 112, first paragraph. Accordingly, Applicants respectfully request reconsideration and withdrawal the rejection.

Rejection Under 35 U.S.C. §102(b)

Claim 1 is rejected under 35 U.S.C. §102(b) as being anticipated by Schulthess *et al.*

(U.S. Patent No. 4,322,405; hereinafter "Schulthess"). The Examiner states that Schulthess discloses oral administration of a bacterial lysate to treat rheumatoid arthritis (RA) and that this method inherently has the property of inducing immune down regulation. The Examiner then concludes that Schulthess "uses the same antigen (bacterial component) and mode of administration (oral administration) encompassed by the claimed method." Office Action page 5.

Applicants respectfully disagree that the claims are anticipated by Schulthess. However, solely in an effort to promote prosecution, claim 1 has been amended to recite that SIDR is produced by components or fragments of streptococcal bacteria. Schulthess discloses the treatment of RA with lysates derived from specific strains of *E. coli*. See Abstract and col 1, lines 5-32. Schulthess does not disclose the use of components or fragments of streptococcal bacteria. To anticipate, a prior art reference "must disclose each and every feature of the claimed invention, either explicitly or inherently." MPEP §2131; *Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 1047 (Fed. Cir. 1995). Schulthess clearly does not anticipate amended claim 1. Applicants respectfully request withdrawal of the rejection.

Rejection Under 35 U.S.C. §103(a)

Claims 1-3 were rejected under 35 U.S.C. §103(a) as unpatentable over Chen *et al.*, (WO 96/39176; hereinafter "Chen") in view of Katz (US Patent No. 4,950,469). The Office Action states that

> Chen et al. teach that oral tolerance to autoantigens can be used to treat antibody mediated autoimmune disease wherein the disease involves antibodies which bind the pertinent autoantigen and wherein oral tolerance is a form of "selective immune down regulation." (see specification, page 17, second paragraph). While Chen et al. do not teach that disease provoking antigen is streptococcus which is involved in the pathogenesis of rheumatic fever, Katz et al. teach that rheumatic fever involves an autoimmune antibody response caused by anti streptococcal antibodies which cross react with human tissues.

Office Action page 10.

Applicants respectfully traverse the rejection. The recently revised Examiner guidelines for assessing obviousness set forth detailed requirements based on asserted rationales for obviousness. The Rationales To Support Rejections Under 35 U.S.C. §103

provide the following possible rationales:

> (A) Combining prior art elements according to known methods to yield predictable results;
>
> (B) Simple substitution of one known element for another to obtain predictable results;
>
> (C) Use of known technique to improve similar devices (methods or products) in the same way;
>
> (D) Applying a known technique to a known device (method or product) ready for improvement to yield predictable results;
>
> (E) "Obvious to try" – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
>
> (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art; and
>
> (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

See MPEP 8th Edition, rev. 6, §2141.

Applicant proceeds with the understanding that this rejection conforms to rationale G quoted above. The MPEP further sets forth the requirements for an obviousness rejection under this rationale:

> To reject a claim based on [rationale G], Office personnel must resolve the Graham factual inquiries. Then, Office personnel must articulate the following:
>
> (1) a finding that there was some teaching, suggestion, or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings;
>
> (2) a finding that there was reasonable expectation of success; and
>
> (3) whatever additional findings based on the Graham factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

> The rationale to support a conclusion that the claim would have been obvious is that "a person of ordinary skill in the art would have been motivated to combine the prior art to achieve the claimed invention and that there would have been a reasonable expectation of success." DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co., 464 F.3d 1356, 1360, 80 USPQ2d 1641, 1645 (Fed. Cir. 2006). **If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.** [emphasis added]

See MPEP 8th Edition, rev 6, §2143

The rationale to support a conclusion that the claim would have been obvious is that "a person of ordinary skill in the art would have been motivated to combine the prior art to achieve the claimed invention and that there would have been a reasonable expectation of success." DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co., 464 F.3d 1356, 1360, 80 USPQ2d 1641, 1645 (Fed. Cir. 2006). If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art. See MPEP 8th Edition, rev 6, § 2143.

Applicants respectfully contend that the combination of Chen in view of Katz does not render amended claim 1 obvious. The Examiner cites to Chen in defining the term "autoantigen" as including an "antigenic substance that induce conditions having the characteristics of an autoimmune disease when administered to mammals." Office Action page 7. However, at the time of the Chen filing there was no evidence in the literature that streptococcal fragments or lysates alone can induce an autoimmune response in a test subject. The teachings of Katz are instructional only in connecting a bacterial infection by streptococcus with induction of rheumatic fever, something that was well known prior to Katz. At the time of the filing it was known only that an active infection by streptococcus and a subsequent immune response to rid the subject of the infectious agent induces rheumatic fever. It was discovered only after the filing of the present invention that, under appropriate conditions, streptococcal proteins may be administered to animals to create an animal model similar to human rheumatic fever. Quinn *et al.*, Infect. Immun 69; 4072-4078 (2001); Gorton *et al.*, 2006 Int. Congress Series 1289 289-292. Streptococcal antigens were not known to satisfy Chen's definition at the time of the filing of the present invention. For instance, the Quinn *et al.* paper cited above specifically states "In this study, we investigated the hypothesis that streptococcal M protein could produce inflammatory valvular heart

lesions similar to those seen in rheumatic fever (RF)" (emphasis added). Page 4072, left column, last sentence.

Thus, contrary to the Examiner's contentions, there was no evidence in the literature that streptococcal fragments or lysates alone can induce an autoimmune response. Thus, one of skill in the art would have no motivation to combine the teachings of Chen and Katz because it was not known that the currently claimed streptococcal fragments or lysates would produce the required response. One would have no expectation that the combination would be effective because, contrary to the Examiners contentions, there was no indication at the time of filing that the streptococcal antigen disclosed by Katz would function as an autoantigen as defined by Chen. Claim 1 is not anticipated by the combination of Chen and Katz. Withdrawal of the rejection is respectfully requested.

CONCLUSION

Applicants respectfully submit that all claims are in condition for allowance. Early notification of a favorable consideration is respectfully requested. In the event any issues remain, Applicants would appreciate the courtesy of a telephone call to their counsel at the number listed below to resolve such issues and place all claims in condition for allowance.

Respectfully submitted,
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